Rejections of the Claims under 35 U.S.C. § 112

Claims 3-12, 14-23, 25-27, 29-34 and 36-46 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that is not described in the specification in such a way as to convey to one skilled in the art at the time the application was filed, that the inventor(s) had possession of the claimed invention. In particular, the Examiner alleges that the phrase "greater than 36% sequence identity with SEQ ID NO:2" is new matter. In what appears to be a second rejection under 35 U.S.C. § 112, first paragraph, the Examiner has asserted that the specification does not provide a correlation between the claimed structure (greater than 36% sequence identity with SEQ ID NO:2) and the claimed function (increases yeast cell growth or protein secretion). Hence, according to the Examiner, claims directed to such a correlation would also contain new matter.

Applicant submits that the specification provides a written description of each and every element of Claims 3-12, 14-23, 25-27, 29-34 and 36-46 that would reasonably convey to one of skill in the art that the inventors were in possession of the claimed invention at the time of filing. However, in order to expedite the prosecution of this application the claims have been amended to embrace vesicular fusion factor 2 proteins comprising SEQ ID NO:2 and conservative variations thereof. Support for subject matter relating to such conservative variation scan be found throughout the specification, for example, at Page 4, Line 18 through Page 5, Line 1 (see especially Page 5, Line #1) and at Page 9, Lines 7-29.

Applicant submits that possession of a claimed genus may be shown by a disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties. Here, the specification discloses the chemical structure of Vff2p (the sequences of SEQ ID NO:1 and SEQ ID NO:2). Moreover, discussion of the types of changes that can be made to the protein sequence to generate a protein with conserved substitutions but with substantially the same or improved qualities is provided, for example, at Page 9, Line 7 to Page 10, Line 28. A teaching that proteins of the cellular secretory pathway are conserved between a number of unlike species is provided, for example, at Page 11, Lines 12-13. Methods for detecting whether protein can increase yeast cell growth or protein secretion are provided, for example, at Page 14,

Line 7 to Page 18, Line 4; Page 19, Line 14 to Page 21, Line 20; and the Examples. Accordingly, one of skill in the art would definitely understand that the inventors were in possession of the claimed subject matter at the time of filing.

Accordingly, the rejections of claims 3-12, 14-23, 25-27, 29-34 and 36-46 under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Claims 3-12, 14-23, 25-27, 29-34, 36-42 and 44-46 remain rejected under 35 U.S.C § 112, first paragraph, because the specification, while being enabling for a polynucleotide with a sequence of SEQ ID NO:1, a protein with a sequence of SEQ ID NO:2, and a host cell (*Saccharomyces cerevisiae*), does not reasonably provide enablement for polynucleotides and/or proteins other than SEQ ID NOs:1 and 2 or a host cell other than *Saccharomyces cerevisiae.*

Applicant submits that the specification enables one of skill in the art to make and use each and every element of Claims 3-12, 14-23, 25-27, 29-34 and 36-46. However, in order to expedite the prosecution of this application the claims have been amended to embrace vesicular fusion factor 2 proteins comprising SEQ ID NO:2 and conservative variations thereof. The specification describes how to make and use such proteins and conservative variations thereof, for example, at Page 9, Lines 7-29.

Applicant further submits that the specification enables one of skill in the art to practice the invention in any yeast species. The Examiner has criticized Applicant's citation to certain cases including *In re Wands*, 8 U.S.P.Q. 1400, 1404 (Fed. Cir. 1988) and *Hybritech Inc. v. Monoclonal Antibodies Inc.*, 231 U.S.P.Q. 81, 84 (Fed. Cir. 1986), because such cases refer to the field of monoclonal antibody technology. The Examiner states that the monoclonal antibody field is well-developed, where it is standard practice to screen hybridomas to identify a desirable monoclonal antibody. Moreover, the Examiner asserts that one of skill in the art knows that a desired antibody could be obtained with sufficient screening. According to the Examiner the field of the instant invention is not as well-developed a field and consequently there is not the same high expectation of success.

Applicant submits that yeast have been manipulated and utilized to generate useful products for far longer than the processes utilized to generate monoclonal antibodies. Yeast genetics are well understood and procedures for making recombinant products using yeast and yeast mutant strains have been in existence for many years. *See, e.g.*, Burke et al., METHODS IN

YEAST GENETICS, Cold Spring Harbor, New York (2001); Barnett et al., YEAST CHARACTERISTICS AND IDENTIFICATION, Cambridge Univ. (3rd ed. 2000). Cloning and transformation procedures are routine when utilizing isolated polynucleotides (e.g.. SEQ ID NO:1). *See, e.g.*, Sambrook et al., GUIDE TO MOLECULAR CLONING: A LABORATORY MANUAL, Cold Spring Harbor, New York (1989); Sambrook et al., GUIDE TO MOLECULAR CLONING: A LABORATORY MANUAL, Cold Spring Harbor, New York (2001). Furthermore, one of skill in the art would have a reasonable expectation of successfully using the vesicular fusion factor 2 proteins of the invention in a variety of yeast species. *See, e.g.* Specification at Page 16, Lines 9-27.

Moreover, whether or not cloning and yeast genetics procedures are as well-developed as monoclonal antibody procedures, the law relating to enablement is the same. A patent applicant need not have prepared and tested all the embodiments of the invention in order to meet the requirements of section 112. *In re Angstadt*, 190 U.S.P.Q. 24, 219 (C.C.P.A. 1976). Enablement is not precluded by the necessity for some experimentation, such as routine screening. The key word is "undue" not "experimentation." *In re Angstadt*, 190 U.S.P.Q. 214, 219 (C.C.P.A. 1976). A considerable amount of experimentation is permissible if it is merely routine, or the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should take. *Ex parte Jackson*, 217 U.S.P.Q. 804, 807 (Bd. App. 1982). Thus, the fact that a given claim may encompass use of a polynucleotide in a number of species is not dispositive of the enablement issue, particularly in an art area in which the level of skill is high and where yeast species have been manipulated for using standard procedures for many years.

Practitioners of the art related to the present application would be well-equipped to utilize polynucleotides or proteins encoding amino acid sequences related to SEQ ID NO:2 in a number of yeast species. The specification further provides methods for using polynucleotides that encode Vff2 proteins, for example, at Page 11, Line 20 to Page 21, Line 20. The specification explicitly discloses how to assess whether there is an increase in yeast cell growth, for example, in Example 3D. Protein secretion can be assessed using methods disclosed in the specification, for example, at Page 14, Line 29 to Page 18, Line 11, and the Examples. Thus, one of ordinary skill in the art would understand from the teachings of the specification how to manipulate the polynucleotides and polypeptides of the invention in a number of species to increase yeast cell

growth or protein secretion. Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is requested.

§102 Rejection of the Claims

Claims 3-7, 11, 12, 14-18, 22, 23, 25, 26, 29, 36, 44 and 45 remain rejected under 35 U.S.C § 102(a) as being anticipated by Powell et al. (Mol. Biol. Cell 10 (suppl): 298a, abstract No. 1727, November 1999, IDS reference).

Applicants submit that this rejection must be withdrawn because the Powell et al. abstract is a publication by the inventors that was published within one year of the filing date of the application. While some authors listed on the abstract are not named inventors of the application, Applicant provides a declaration stating that Shoetal K. Patel and Ya-Lin Sun, who were named authors on the abstract, merely worked under the direction and supervision of Kendall S. Powell and Martin Latterich and did not contribute to the conception of the subject matter claimed in the application. Accordingly, Applicant respectfully requests withdrawal of this rejection under 35 U.S.C § 102(a).

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (516-795-6820) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Box AF, Commissioner of Patents, Washington, D.C. 20231, on this 26th day of September, 2002.

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Name

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Signature